



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 117 and 507

[Docket No. FDA-2016-D-1164]

Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food); Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry entitled “Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food).” This draft guidance explains our current thinking on how to determine whether a business is a “qualified facility” that is subject to modified requirements under our rule entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” (the Preventive Controls for Human Food Rule) or under our rule entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals” (the Preventive Controls for Animal Food Rule). This draft guidance also explains our current thinking on how a business would submit Form FDA 3942a attesting to its status as a qualified facility under the Preventive Controls for Human Food Rule and how a business would submit Form FDA 3942b attesting to its status as a qualified facility under the Preventive Controls for Animal Food Rule. We also are announcing an opportunity for public comment on

the proposed collection of information embodied in Forms FDA 3942a and 3942b. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and allow 60 days for public comment in response to the notice.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments by [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments on the proposed collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2016-D-1164 for “Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food).” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its

consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance and proposed forms to Food and Drug Administration (HFS-681), 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to this draft guidance for human food facility: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2166.

With regard to this draft guidance for animal food facility: Jeannette Murphy, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6246.

With regard to this proposed collection of information: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAstaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production.

Section 103 of FSMA amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 418 (21 U.S.C. 350g) with requirements for hazard analysis and risk-based preventive controls for facilities that produce food for humans or animals. We have established regulations to implement these requirements within subparts C and G of the Preventive Controls for Human Food rule (21 CFR part 117) and within subparts C and E of the

Preventive Controls for Animal Food Rule (21 CFR part 507). A business that meets the definition of a “qualified facility” (see 21 CFR 117.3 or 21 CFR 507.3) is subject to modified requirements in § 117.201 of the Preventive Controls for Human Food Rule or in § 507.7 of the Preventive Controls for Animal Food Rule. These modified requirements require the business to submit a form to FDA, attesting to its status as a qualified facility. Section 418(l)(2)(B)(ii) of the FD&C Act directs FDA to issue a guidance related to the documents required to be submitted to FDA to show status as a qualified facility.

In accordance with section 418(l)(2)(B)(ii) of the FD&C Act, we are announcing the availability of a draft guidance for industry on qualified facility attestation. Section II of this draft guidance explains how to determine whether your business meets the definition of “qualified facility” under the Preventive Controls for Human Food Rule and how to submit Form FDA 3942a: Qualified Facility Attestation for Human Food Facility, attesting to its status as a qualified facility under the Preventive Controls for Human Food Rule. Section III of this draft guidance explains how to determine whether your business meets the definition of “qualified facility” under the Preventive Controls for Animal Food Rule and how to submit Form FDA 3942b: Qualified Facility Attestation for Animal Food Facility, attesting to its status as a qualified facility under the Preventive Controls for Animal Food Rule.

Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register

concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we also are publishing this notice of the proposed collection of information set forth in this document and seeking public comment.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

The draft guidance entitled "Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)" contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501-3520). A description of these provisions is given below with an estimate of the associated annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to

minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food)

Description: This draft guidance describes FDA procedures regarding the submission of attestations as established under both the Preventive Controls for Human Food Rule and Preventive Controls for Animal Food Rule. Proposed forms FDA 3942a and FDA 3942b have been developed for use by a business in reporting its status as a “qualified facility” under the applicable regulations.

Description of Respondents: Respondents to the collection of information are owners, operators or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States asserting that a facility is a “qualified facility” under applicable FDA regulations.

We estimate the burden for this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Guidance Section	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Section II; Human Food	3942a	37,134	0.5	18,567	0.5 (30 minutes)	9,284
Section III; Animal Food	3942b	1,120	0.5	560	0.5 (30 minutes)	280
Total						9,564

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Consistent with the estimates found in our Preventive Controls for Human Food Rule, we calculate that approximately 37,134 human food facilities will spend approximately 30 minutes (0.5 hour) reporting their status as such to FDA every 2 years. Thus, dividing this figure by 2 to

determine the annual burden, we estimate there will be a total of 18,567 responses and a total of 9,284 burden hours associated with this collection element.

Similarly, and consistent with the estimates found in our Preventive Controls for Animal Food Rule, we estimate that approximately 1,120 animal food facilities will spend approximately 30 minutes (0.5 hour) reporting their status as such to FDA every 2 years. Thus, dividing this figure by 2 to determine an annual burden, we estimate there will be a total of 560 responses and a total of 280 burden hours associated with this information collection element.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in part 117 have been approved under OMB control number 0910-0751. The collections of information in part 507 have been approved under OMB control number 0910-0789.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance, including its appendices containing instructions for filling out Forms FDA 3942a and 3942b and the proposed Forms FDA 3942a and 3942b, at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: May 10, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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